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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR. | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/687,483 | 10/13/2000 | Hubert Koster | 24736-2033 | 7859 |

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EXAMINER

CLOW, LORI A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 05/13/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,483

Applicant(s)

KOSTER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-17, 30-34, 43-54, 60-64, 71-81, 83-85 and 98-100 is/are pending in the application.
- 4a) Of the above claim(s) 32, 33, 34, 60-64, 71-81, 83-85, and 100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-17, 30, 31, 43-54, 98 and 99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 11. 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group II in Paper No. 12 is acknowledged. The traversal is on the ground(s) that Group II is related to each of Groups IV and XVI as a subcombination/combination. This is not found persuasive because the system for high throughput processing of biological samples does not necessarily have to be utilized to analyze the biomarkers of said invention. Furthermore, said invention could be practiced without the system of high throughput analysis, for example by traditional serum level analysis. Therefore, the restriction is maintained and only Group II will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims Objections

Claim 43 is objected to because of the following informalities: Claim 43 is a duplicate of claim 4. Appropriate correction is required.

Claims Rejections-35 USC 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-17 are rejected under 35 U.S.C. 101 because the method of producing a database which simply manipulates data by gathering information and entering it ~~Claims 1-13~~ ^{is non-statutory.}

~~rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject~~

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~~matter~~. Although one could argue that the database could be useful in further research to identify potential risk for patients, there is no specificity identified as to what types of risks are being assessed. Therefore, the invention does not meet the standard of being immediately useful. The need to do extensive work after generating the library does not meet the “concrete, tangible, and useful” result standard set forth in MPEP 2106.

MPEP 2106: “For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing *O’Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible, and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible, and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible, and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and /or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)).”

Claims Rejections-35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-17, 30, 31, 43-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al. (WO 98/35609). Specifically, Campbell et al. teach a computer-based system for predicting the future health of an individual based upon acquiring and analyzing a number of biological and physiological biomarkers. The system comprises a method of obtaining data from healthy members of the population. In particular, the term “specified biological condition” of the invention includes all ranges of health, from the most robustly healthy to the most severely diseased (page 22, lines 13-16). Data could include body tissue or fluids, thus meeting the limitations of claims 4 and 5 and related claims. Biomarker values from individuals in a test population are generated statistically (page 7, line 8), meeting the limitations of claims 5-8 and related claims that include datapoint generation. The individual, be it human or otherwise, is identified by a wide range of biomarkers. In particular, these biomarkers could include physiological and biochemical parameters relating to nutritional, toxicological, genetic, hormonal, viral, infective, lifestyle, and other states (page 9, lines 8-12). In fact, anything that acts as a biological indicator could be used as a biomarker, including genetic data gathered from sources such as VNTR's and RFLP's, as well as a urine test or frequency of smoking (page 19, lines 8-10).

Claims Rejections-35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 98/35609) and further in view of Koster et al. (US 6,043,031). Campbell et al. discloses the use of computer-based system for predicting the future health of an individual based upon acquiring and analyzing a number of biological and physiological biomarkers, as stated above, thus meeting the limitations of the database requirement of claims 98 and 99 (page 22, lines 13-16). Campbell et al., however fail to specifically teach the use of the database with a mass spectrometer or an automated process line that would be used for data gathering, as recited in the claims.

It would however have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Campbell et al. so as to include the further step of

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using a mass spectrometer and an automated line for analysis as taught in Koster et al. Koster et al. suggest the use of mass spectrometry to diagnose a predisposition to a disease or to determine identity or heredity (see abstract). Koster et al also suggest the use of simultaneous detections (multiplexing) and parallel processing in order to expedite analysis (column 4, lines 20-25), thus meeting the limitation of an automated line. One having ordinary skill in the art would have been motivated to incorporate this method of data gathering into the database methods of Campbell et al. based on the fact that Campbell et al. teach the use of any method to gather biomarker data.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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May 7, 2002

Lori A. Clow, Ph.D.

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Lori A. Clow

MKG

MARY K. ZEMAN
PRIMARY EXAMINER

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